REMARKS

Claims 6 and 12 are pending in the present application.

At the outset, Applicants wish to thank Examiner Aughenbaugh for the helpful and courteous discussion with their undersigned Representative on March 24, 2005. During this discussion Applicants' Representative explained the meaning of the term "saturation adsorption amount" and discussed its relevance to the prior art, as well as discussed amendments to address the indefiniteness rejections. The content of this discussion is believed to be reflected in the amendments and remarks set forth herein. Reconsideration of the outstanding rejections is requested.

The rejections of Claims 6, 7, and 12 under 35 U.S.C. §103(a) over:

(a) Fox in view of Waki et al and further in view of Applicants' alleged admission;

(b) Levy et al in view of Waki et al and further in view of Applicants' alleged admission; and

(c) Buechler in view of Waki et al and further in view of Applicants' alleged admission;

are respectfully traversed. In addition, the Examiner's maintained rejection of Claim 12 appearing in paragraph 3 on page 2 of the outstanding Office Action is respectfully traversed.

In the Office Action, the Examiner has continued to maintain the rejection of the claims as being indefinite and obvious in view of the aforementioned combination of references. It is the Examiner's position that the saturation adsorption amount is a function of the molecules placed into the container and not of the polymer used in the container. During the discussion between Applicants' Representative and the Examiner, it became apparent that

the Examiner's confusion is that he is interpreting the term saturation adsorption amount as a solution based parameter and not the theoretical maximum binding capacity of the inner surface of the claimed container for immunoassay, which is the true meaning of this term.

The Examiner's confusion seems to arise from the disclosure at page 7, line 18 to page 8, line 26 of the specification (in particular page 7, line 18 to page 8, line 8). However, close inspection of this section reveals that it defines the terms "adsorption amount." Specifically, this statement defines the *adsorption amount* as varying with the "identify of the molecules, temperature, concentration of the solution, and the pH of the solvent" and then provides as a statement that "the saturation adsorption amount of the molecules used in the immunoassay is 1×10^{-1} pmol/cm^2 or less under the specific conditions—in terms of concentration of the solution, temperature, and pH of the solvent—under which the reaction and assay are carried out."

This latter statement is not intended to define the saturation adsorption amount as being solution dependent. Applicants submit that the actual adsorption amount is concentration and solution dependent and, therefore, varies as a function of specific conditions. However, the *saturation* adsorption amount is a synonymous with the adsorption amount that a given coated surface can support irrespective of the conditions assayed. To further the Examiner's understanding, Applicants provide the following further explanation.

Adsorption is induced by the interaction (adsorption force) between the molecules existing in the container and the inner surface of the container, and the saturation adsorption amount is determined by the combination of the properties of the molecules existing in the container and the base material. The large portion of the adsorption force is generated by the hydrophobic interaction and the electrostatic interaction. Therefore, the saturation adsorption amount is increased according to the combination of the hydrophobic molecules and the

hydrophobic surface of the container, as well as the combination of the molecules carrying a negative charge and the container surface carrying a positive charge.

In contrast, if the inner surface of the container contains no hydrophobic moiety and carries no electric charge, the adsorption force cannot be generated regardless of the changes of solution concentration, temperature and pH, because neither the hydrophobic interaction nor the electrostatic interaction occurs between the molecules existing in the container and the inner surface of the container. The primary cause of the change of adsorption amount brought by solution based parameters is the phenomenon characterized by the exposure of the hydrophobic residue of protein to the container surface, or by the reversal of electric charges of protein, attributed to the structural change of protein. Therefore, if the surface of the container contains no hydrophobic moiety and carries no electric charge, the adsorption does not take place regardless of any changes in solution based parameters (i.e., saturation has been reached).

In view of the foregoing, Applicant submit that the Examiner's interpretation of the saturation adsorption amount as being the maximum adsorption amount of protein emerging under certain solution-based parameters is misplaced. There is a fundamental difference in the adsorption amount and the saturation adsorption amount, which can be recognized from the above. Specifically, the saturation adsorption amount in the present invention is synonymous with the maximum adsorption amount attributed to the surface of the container, and this amount represents the maximum adsorption amount which can not be exceeded regardless of the change of solution-based parameters. Therefore, Applicants submit that Claim 12 *is* definite.

Moreover, Applicants submit that when the present invention is properly interpreted, the invention is not obvious in view of the cited art of record. Specifically, Applicants submit

that the art of record does not disclose or suggest a container for an immunoassay that is coated with an ultra-hydrophilic polymer which is a copolymer containing a (2-methacryloyloxyethylphosphorylcholine) polymer subunit, as presently claimed (see Claim 12). More specifically, Applicants submit that the art of record fails to disclose a copolymer containing a (2-methacryloyloxyethylphosphorylcholine) polymer subunit, much less a container for an immunoassay, wherein the inner surface, which is to contact a specimen for immunoassay, of the container is formed from or coated with the this copolymer and wherein the saturation adsorption amount of molecules used for the assay, on at least an inner surface of the container, is 1×10^{-3} pmol/cm^2 or less.

To this end, Applicants resubmit the following arguments, which were set forth in the response filed on October 20, 2004 and request reconsideration in view of the proper interpretation of the presently claimed invention.

Citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), MPEP §2143.03 states: "To establish a prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." Applicants submit that the disclosure of the art of record, in any combination, fail to meet this requirement and, as such, the artisan would have no reasonable motivation to produce a container for an immunoassay as presently claimed or any reasonable expectation of the advantageous obtained thereby.

The Examiner cites Buechler, Fox, and Levy et al as providing containers for immunoassay, while Waki et al disclose copolymers containing a 2-methacryloyloxyethylphosphorylcholine subunit. Although Waki et al disclose the use of a copolymer closely resembling that of the present invention, this reference does not disclose or suggest that at least an inner surface of the container is coated beforehand with such a copolymer. Moreover, the copolymer disclosed by Waki et al is soluble in water, not

insoluble in water. Further, at no point do Waki et al disclose or suggest that the saturation adsorption amount of 1 x 10^{-3} pmol/cm^2 or less as presently claimed.

Applicants direct the Examiner's attention to Table 5 from Waki et al, which relates to the adsorption of plasma protein, in which the adsorption of plasma protein has been recalculated in terms of the unit "pmol/cm^2" (i.e., the units in the claimed invention). These data clearly show that there is a significant difference between the adsorption amount of plasma protein disclosed by Waki et al and the range claimed in the present invention. In fact the adsorption amount disclosed by Waki et al (i.e., 2-90 pmol/cm^2) is approximately 1000-10000 times more than the saturation adsorption amount defined by the present invention. Therefore, Applicants submit that there is no reasonable expectation based on the disclosure of Waki et al that the saturation adsorption amount as presently claimed can ever be attained. None of Buechler, Fox, and Levy et al compensates for deficiency or provides motivation to attain such a limitation.

Further, the container for a immunoassay of the present invention comprises a significantly specific feature such that at least the inner surface of the container, more specifically the entire surface of the container, is coated beforehand with an insoluble ultra-hydropbilic polymer containing a 2-MPC polymer and the saturation adsorption amount of protein falls within the range of 1 x 10^{-3} pmol/cm^2 or less. More specifically, the container of the present invention absorbs almost no protein on its inner surface and therefore never becomes a solid state. For immunoreactions to be effectively performed by use of the container of the present invention, it is necessary either to employ a homogeneous assay or to incorporate other solid phase substances (e.g., beads) in the container. This technical conception is neither disclosed nor suggested in the art of record.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection of Claim 12 under 35 U.S.C. §112, second paragraph, and the rejections of the pending claims under 35 U.S.C. §103.

The new rejection of Claims 7 and 12 under 35 U.S.C. §112, second paragraph, as set forth in paragraph 5 on page 3 of the outstanding Office Action and the maintained rejection of Claim 7 appearing in paragraph 2 on page 2 of the outstanding Office Action are obviated by amendment.

Applicants have canceled Claim 7 and have amended Claim 12 to remove the ambiguity related to the inclusion of the term "of molecules." In view of these amendments, these grounds of rejection are no longer believed to be tenable.

Withdrawal of these grounds of rejection is requested.

Finally, Applicants again request that the Examiner provide acknowledgment that the references cited on the Information Disclosure Statements filed on February 14, 2002, have been considered. Applicants respectfully request that the Examiner acknowledge consideration of same by providing Applicants with initialed copies of the Form PTO-1449 filed on the aforementioned date. For the Examiner's convenience, a copy of Form PTO-1449 as originally filed on February 14, 2002, is **enclosed herewith**.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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Form PTO 1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

LIST OF REFERENCES CITED BY APPLICANT

ATTY DOCKET NO.	SERIAL NO.
210131US0PCT	09/857,214
APPLICANT: Hayao TANAKA	
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4 472 357	09/18/84	Didya D. LEVY et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO
	AO	0 137 292	04/17/85	EP		No
	AP	08-033472	02/06/96	JP		No
	AQ	1 401 233	07/16/75	GB		No
	AR					
	AS					
	AT					
	AU					
	AV					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	
	AX	
	AY	
	AZ	☐ Additional References sheet(s) attached

Examiner	Date Considered

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.